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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,887	10/12/2005	Villoo Morawala Patell	20049.1USWO	4453
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HAMRE, SCHUMANN, MUELLER & LARSON, P.C.			KUMAR, VINOD	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,887	Applicant(s) PATELL, VILLOO MORAWALA	
	Examiner VINOD KUMAR	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-20 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 January 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Objections and Rejections

1. Claim amendment filed in the paper of February 26, 2008 is entered. Applicant's amendment to the specification, drawings and response to Office action filed in the paper of January 18, 2008 are also entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 17-20 and 23-25 are pending.

Claims 1-16, 21-22 and 26-28 are cancelled.

Claims 17-20 and 23-25 are examined on merits in this Office action.

Objections to the specification and drawings are withdrawn in light of amendments to the specification.

Objections to claims 17, 18 and 23-25 are withdrawn in light of claim amendment filed in the paper of February 26, 2008.

Election/Restrictions

2. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

3. Claims 19 and 20 are objected to because of following informalities:

Claim 19 is objected for designating Cassava vein mosaic virus as CaMV. The art related to promoter(s) designates CaMV as cauliflower mosaic virus.

In claim 20, it is suggested to change "a terminator used is a NOS terminator" to -
-said MnSOD coding sequence is further operably linked to a NOS terminator--.

Claim Rejections - 35 USC § 112

4. Claims 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 23 and 24 recite "30-95%" which introduces **NEW MATTER** into amended claim. The specification does not provide written description support for "30-95%". This does not comply with written description requirements.

This rejection has been necessitated due to the claim amendment filed in the paper of January 18, 2008.

Claim Rejections - 35 USC § 103

5. Claims 17-20 and 23-25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bowler et al. (European Patent Publication No. EP 0359617A2,

Art Unit: 1638

Published March 21, 1990, Applicant's IDS) in view of Tanaka et al. (Plant Science, 148:131-138, 1999) for the reasons of record stated in the Office action mailed November 18, 2008. Applicant traverses the rejection in the paper filed January 18, 2008.

Applicant argues that monocotyledonous and dicotyledonous plants have diverged significantly and may display differences in response to perturbations such as stress and may respond differently to transgenic events such as a plastidic localization of MnSOD (response, page 7, lines 25-28). Applicant further argues that it has been well established that Indica and Japonica groups can be separately classified under *Oryza sativa* based on physiological and morphological traits including drought tolerance, potassium chlorate resistance, phenol reaction, plant height and leaf color. Applicant further argues that Japonica and Indica rice varieties have physiological differences, and Tanaka et al. do not suggest transforming Indica rice variety that would result in a transgenic plant resistance to salt stress. Applicant further argues that Tanaka et al. suggest at page 13 under discussion that correlation of salt tolerance with antioxidant enzyme levels have remained controversial (response, page 8, lines 12-30). Applicant further argues that Bowler et al. provide no indication that their construct will work in a monocotyledonous plant (response, lines 7-12).

Applicant's arguments were fully considered but were deemed to be unpersuasive.

It is maintained that Bowler et al. teach a method of making a transgenic plant cell of *Nicotiana plumbaginifolia* with increased superoxide dismutase production,

Art Unit: 1638

comprising transformation of said plant cell with a DNA construct, which comprises a 35S CaMV promoter, operably linked with a nucleotide sequence encoding a superoxide dismutase derived from *Nicotiana plumbaginifolia* L., and wherein, the 5' end of said superoxide dismutase coding sequence is operably linked with a nucleotide sequence encoding a pea ribulose-1-5-bisphosphate carboxylase transit peptide sequence, and wherein the 3' end of said superoxide dismutase sequence is further operably linked to a NOS terminator. The transgenic plant cells were regenerated to obtain a mature transgenic plant comprising said DNA construct. The transgenic plants also exhibited higher levels of superoxide dismutase production. The reference further teaches that said transgenic plants also exhibited increased tolerance to environmental stresses. The reference also teaches that increased SOD production in a plant cell results in increased resistance to pathogen attack. See in particular, page 2, lines 1-35; page 3, lines 50-60; page 4, lines 20-38, lines 63-65; page 5, lines 1-59; page 6, lines 5-24 and 39-59; page 8, line 61 to line 50 of page 10; page 11, lines 5-15; page 12, line 1 to page 13, line 45; page 16, line 49 to page 17, line 15. The reference also teaches that SOD activity was doubled (which is greater than 30%) in the transgenic plants overexpressing MnSOD (see page 11, lines 55-56).

It is further maintained that Tanaka et al. teach making a transgenic plant cell of rice with increased superoxide dismutase production, comprising transformation of said plant cell with a DNA construct, comprising a 35S CaMV promoter operably linked with a yeast SOD coding sequence which is operably linked with a NOS terminator. The 5' end of the SOD coding sequence is operably linked with a nucleotide sequence

Art Unit: 1638

encoding a chloroplast transit peptide signal. The transgenic plant cells are regenerated to obtain a mature transgenic plant of rice comprising said DNA construct. The transgenic plants also exhibited higher levels of superoxide dismutase production. The reference further teaches that said transgenic plants also exhibited increased tolerance to environmental stresses, and displayed higher yield under said environmental stress conditions. See in particular, page 131, abstract; page 132, materials and methods; page 134, figure 3; page 135, figures 4-6; page 136, figure 7. The reference also teaches that the transgenic rice plants exhibited more than 1.5 fold (means greater than 30%) increase in Mn-SOD activity under NaCl stress.

It is therefore maintained that it would have been prima facie obvious and within the scope of an ordinary skill in the art at the time the invention was made, to modify the method of making a stress-tolerant transgenic plant as taught by Bowler et al., by transforming any salt-sensitive cultivated rice variety, including salt sensitive Indica rice varieties, such as Godavari 8 or Salween 2, with Bowler et al. DNA construct, using any method of plant transformation including the rice transformation method of Tanaka et al. to obtain the transgenic Indica rice variety expressing Bowler et al. Mn-SOD protein in the transgenic Indica rice varieties with a reasonable expectation of success.

It is further maintained that given Bowler et al. teach that SOD gene expression in plastids increases environmental stress tolerance in the transgenic plant, one of ordinary skill in the art would have been motivated to express Bowler et al. DNA construct in any stress sensitive variety of rice including the Godavari 8 or Salween to arrive at the instantly claimed invention with a reasonable expectation of success.

It is further maintained that it would have been obvious to expect that said environmental stress tolerant transgenic rice variety would have exhibited increased shelf life and improved (higher) yield under environmental stress conditions, compared to a non-transformed control plant.

It is important to note that claim 19 is reciting Cassava vein mosaic virus as CaMV promoter but the state of the art teaches that CaMV is a cauliflower mosaic virus. Since CaMV is recited in the claim, Bowler et al. or Tanaka et al. 35S CaMV addresses this limitation.

Also it would have been obvious and within the scope of an ordinary skill in the art to use any constitutive promoter including a Cassava vein mosaic virus promoter that were known to be active in rice to arrive at the claimed invention with a reasonable expectation of success.

Applicant is reminded that the issue is not whether monocots are physiologically different from dicots in responding to MnSOD localization to plastids, or whether physiological differences existed among different varieties of rice. Rather, the issue is whether there was any suggestion in the prior art at the time the claimed invention was made to suggest that one of ordinary skill in the art would have been motivated to overexpress MN-SOD in rice. Given Tanaka et al. clearly suggests making salt tolerant transgenic rice overexpressing chloroplast targeted MnSOD, one of ordinary skill in the art would have been motivated to transform any cultivated rice variety included Indica varieties with Bowler et al. DNA construct to arrive at the instantly claimed invention with reasonable expectation of success.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious and within the scope of an ordinary skill in the art to combine the teachings of Bowler et al. and Tanaka et al. to arrive at the instantly claimed invention with a reasonable expectation of success.

Thus it is maintained that the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art.

Conclusions

6. Claims 17-20 and 23-25 remain rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is set to expire within TWO MONTHS of the mailing date of this final action and the advisory action is

Art Unit: 1638

not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)272-0975. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong T. Bui/

Primary Examiner, Art Unit 1638